



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,575	11/28/2000	Dale B. Schenk	15270-005912	6096
20350	7590	02/12/2004	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			NICHOLS, CHRISTOPHER J	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 02/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b>	<b>Application No.</b> 09/724,575	<b>Applicant(s)</b> SCHENK, DALE B.	
	<b>Examiner</b> Christopher Nichols, Ph.D.	<b>Art Unit</b> 1647	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 29 December 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. **ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).**

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 29 December 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see continuation sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: \_\_\_\_\_

Claim(s) rejected: 11-19, 21-25, 58-73

Claim(s) withdrawn from consideration: \_\_\_\_\_

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☒ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
10. ☐ Other: \_\_\_\_\_

## ADVISORY ACTION

### *Status of Application, Amendments, and/or Claims*

1. The Amendment and Response filed 29 December 2003 has been received and entered in full. Claims 1-10, 20, and 26-57 have been cancelled. Claims 58-73 have been added. Claim 11 has been amended. Claims 11-19, 21-25, and 58-73 are under examination.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The objection to claims **13, 15, 16, 60, 62, and 63** as set forth at pp. 4 ¶10 of the previous Office Action (25 July 2003) is maintained. Until a decision is reached concerning the Applicant's Petition (30 December 2003), said claims contain unelected material. The restriction requirement is still in effect and therefore the objection is maintained.
4. Claims **11-19, 21-26, and 58-73** are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *practicing the methods as claimed for treatment in claims 11-19 and 21-26 and for prophylaxis in claims 58-73 wherein said disorder is Alzheimer's disease and said agent is A $\beta$ 42, A $\beta$ 1-40, A $\beta$ 1-12, A $\beta$ 13-28, or A $\beta$ 1-5* does not reasonably provide enablement for *other disorders or other agents*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to **make or use** the invention commensurate in scope

Art Unit: 1647

with these claims is *maintained in part* for the reasons as set forth at pp. 4-10 ¶11-28 in the previous Office Action (25 July 2003).

5. The crux of Applicant's argument lies on the belief that disclosing a strategy to achieve a desired therapeutic result is sufficient to meet the enablement requirement of 35 U.S.C. ¶112. The Examiner respectfully disagrees. Applicant has demonstrated that certain fragments may be used in an active immunization protocol to treat or be used in prophylaxis in Alzheimer's disease. Further the use of an anti-synuclein antibody is not of relevance to the claims as presented which are drawn to a method of active not passive immunization. The Examiner used *In re Wands* in the context of establishing a lack of enablement argument (see MPEP §2164.01). Therefore the argument consists of an invitation to experiment in the absence of concrete guidance as to accomplish the full breadth of the claims as instantly presented.

6. The rejection of claims **11-19**, **21-26**, and **57-73** are under provisional obvious-type non-statutory double-patenting as set forth at pp. 11-13 ¶21-28 in Office Action (2 November 2002) is *maintained*.

7. The rejection of claims **11-19**, **21-26**, and **57-73** are under provisional obvious-type non-statutory double-patenting as set forth at pp. 10-11 ¶29 in Office Action (25 July 2003) is *maintained*.

Art Unit: 1647

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on **(571) 272-0887**. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CJN  
February 9, 2004

  
**GARY KUNZ**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**